



Department of Health Professions

Virginia Board of Pharmacy Law Update

VSHP Spring Seminar March 25, 2011

**Caroline Juran, Executive Director
Sammy Johnson, Deputy Executive Director**



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Program Objectives

- Explain routine pharmacy inspection process
- Amendment of 18VAC110-20-490 regarding automated dispensing devices
- Briefly review select legislative bills which could impact healthcare professionals



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Board Inspection Process



Routine Inspection Process

- At the conclusion of a routine inspection:
 - inspection summary will be provided;
 - expedited prehearing consent order imposing a monetary penalty may be provided.
- Monetary penalties derived from guidance document 110-9.

http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm



Routine Inspection Process

- 110-9 lists “major” deficiencies and “minor” deficiencies that will result in imposing a monetary penalty.



Routine Inspection Process

- Citing of any major deficiency = monetary penalty.
- Citing of 1 or 2 minor deficiencies = no monetary penalty.
- Citing of 3 minor deficiencies = monetary penalty of \$250.
- \$100 monetary penalty added for each additional minor deficiency cited.



Routine Inspection Process

- Thresholds included in 110-9 to clarify when pharmacy is not in substantial compliance.
- Increases consistency amongst pharmacy inspectors.
- Eliminated some deficiencies that Board will not inspect for now, e.g., posting of licenses.



Routine Inspection Process

- New inspection process:
 - expedites disciplinary process associated with inspections;
 - reduces costs associated with required scheduling of informal conferences, e.g., travel costs for Board members and licensees, administrative overhead, etc.



Question

Does the Board benefit financially from the collection of monetary penalties?



Question

- No!
- Monetary penalties do NOT remain with the Board.
- All monetary penalties must be transferred by law to the Virginia Literary Fund.



Routine Inspection Process

- Examples of major deficiencies:
 - No PIC or PIC not fully engaged in practice at pharmacy location;
 - Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists;
 - Unauthorized access to alarm or locking device for Rx department;



Routine Inspection Process

- Examples of major deficiencies:
 - Refrigerator/freezer temperature out of range or not monitored (± 4 degree = *threshold*);
 - No biennial inventory, or *over 30 days late = threshold*;
 - No incoming change of PIC inventory taken *within 5 days = threshold*.



Routine Inspection Process

- Examples of minor deficiencies:
 - No hot/cold running water;
 - Biennial taken late but *within 30 days = threshold*;
 - Records of receipt (invoices) not on site or retrievable;
 - Repackaging records and labeling not kept as required or in compliance – *10% threshold*.



Routine Inspection Process

Two options for resolving inspection with deficiencies:

1. Within 30 days of receiving the notice, submit to the Board office:
 - signed prehearing consent order;
 - documentation that all deficiencies have been corrected;
 - payment for the monetary penalty.
2. Request in writing an informal conference for hearing the matter.
 - could result in disciplinary sanctions in addition to the monetary penalty listed on the prehearing consent order.



Routine Inspection Process

- Prehearing consent order is:
 - issued against the pharmacy permit;
 - a public document.



Routine Inspection Process

- 13 hospital pilot inspections performed July through December 2010:
 - 0 = No deficiency
 - 4 = deficiency cited with no monetary penalty
 - 9 = deficiency cited with monetary penalty



Frequently Cited Deficiencies

- **perpetual inventory** (major 15) of all Schedule II drugs received and dispensed shall be performed with reconciliation at least monthly.
- ***Board amended this deficiency on March 9th may now be performed as early as seven days prior to the applicable calendar month and as late as seven days after the applicable calendar month***



Frequently Cited Deficiencies

- Acceptable example of performing perpetual inventory:
 - November 10, 2010 (November inventory)
 - November 30, 2010 (December inventory)
 - February 4, 2011 (January inventory)



Frequently Cited Deficiencies

- **biennial inventory** (major 13 and minor 12) taken on any date within two years of the previous biennial inventory
 - ***physical count, not an estimate, of CI – V drugs (incorrect, refer to guidance document 110-16);
 - includes expired drugs.
- ***Guidance document 110-16 approved on March 9th clarifying whether physical count is required.



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Guidance document 110-16

- those persons required in law to perform an inventory of drugs shall physically count all drugs in Schedules II-V when a theft or loss of drug has occurred;
- may otherwise perform the inventory in a manner consistent with federal allowances which require a physical count of drugs in Schedule II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules; and,
- nothing would prevent a person when performing an inventory from choosing to physically count all drugs in Schedules II-V.



Frequently Cited Deficiencies

- **incoming PIC inventory** (major 14 and minor 13)
 - physical count, not an estimate, of CI – V drugs*** (incorrect, refer to guidance document 110-16);
 - includes expired drugs;
 - completed as of the date the individual becomes PIC and prior to opening for business on that date.



Frequently Cited Deficiencies

- **Pharmacist not checking** and documenting repackaging, compounding, or bulk packaging (major 20)
 - Must be able to demonstrate which pharmacist verified accuracy of every dispensed drug



Frequently Cited Deficiencies

- If pharmacy is not open 24/7, **security system** be capable of sending an alarm signal to the monitoring entity when breached if the primary communication line is not operational (major 9).



Frequently Cited Deficiencies

- If **emergency key** or other means of unlocking the prescription department and the alarm access code maintained (minor 8):
 - Place sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy.
 - In lieu of the pharmacist's signature across a seal, the executive director for the Board may approve other methods of securing the emergency access. When approved, strongly recommended to maintain letter of approval.



Frequently Cited Deficiencies

- Pharmacy's **refrigerator or freezer** is not monitored by a thermometer or the temperature varies from that required by regulation (major 8 and minor 5).



Frequently Cited Deficiencies

- **Monthly audit of automated dispensing devices** (minor 38)
 - audit shall include a review of administration records from *each* device per month for possible diversion by fraudulent charting
 - audit shall include *all Schedule II-V drugs* administered for a time period of not less than *24 consecutive hours* during the audit period.



Frequently Cited Deficiencies

- **Monthly audit of automated dispensing devices** (minor 38)
 - Inspector will review audits associated with 3 months
 - Deficiency will be cited for 10% or more non-compliance
 - Ex: if 20 ADDs in hospital, in 3 months should have done 60 audits; if missing 6 or more audits, or 6 or more incomplete, then not in compliance



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Tips for Preparing for a Routine Inspection

- Perform a self-inspection using applicable sections of inspection report found at http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm
- Get organized by creating a folder containing locations of information inspector will need to review.



Tips – Create a Folder Containing:

- Inventories (biennial and PIC changes) performed within the last 2 years;
- Location of invoices
 - Schedule II----2 years
 - Schedule III-V----2 years
 - Schedule VI----since September 2009



Tips – Create a Folder Containing (cont.):

- Location of dispensing data verification for previous 2 years
 - Printout
 - Separate File
 - Bound Log Book



Tips – Create a Folder Containing (cont.):

- Location of records of destruction for previous 2 years;
- Location of repackaging records for previous 1 year;
- Location of applicable policies and procedure manuals;



Tips – Create a Folder Containing (cont.):

- List of pharmacists and pharmacy technicians employed, both full time and part-time;
- If have pharmacy technician trainee:
 - Documentation indicating date enrolled in Board-approved pharmacy technician training program, progress, and completion date
- Documentation of site specific technician training program.



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Regulation 18VAC110-20-490

Automated devices for dispensing and
administration of drugs



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18VAC110-20-490

- 2009 - petition for rule-making to eliminate requirement for nurse's signature on delivery record at time of loading Schedule II-V drugs in ADD.
 - impacted patient care by pulling nurses during a nursing shortage
 - Hospitals use activity reports to ensure delivery and security of drugs.



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18VAC110-20-490

- Board adopted proposed amendment.
- Regulatory change became effective March 17, 2011.



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General Assembly 2011

Select Legislative Bills which MAY
Impact Pharmacy and
Other Bills of Interest



HB 1762

- Places 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), a hallucinogenic substance found in psychoactive toads and plants, into Schedule I.
- 01/18/11 House: Passed by for the day in Health, Welfare and Institutions
- **Did Not Pass**



HB 2464

- Places immediate precursor to fentanyl, 4-anilino-N-phenethyl-4-piperidine (ANPP) into Schedule II which conforms to DEA scheduling.
- **Passed**



HB 2220

- Requires pharmacies to implement a continuous quality improvement program, according to Board regulations, to provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors.



HB 2220

- Pharmacies actively reporting to a patient safety organization that has as its primary mission CQI under the Patient Safety and Quality Improvement Act of 2005 deemed in compliance with this section.
- **PASSED**



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HB 2255/SB 1029

- Clarifies that nothing in the Health Records Privacy Act shall prohibit a health care provider who dispenses a controlled substance to a patient from disclosing information obtained from the Prescription Monitoring Program and contained in a patient's health care record to another health care provider when such disclosure is related to the care or treatment of the patient.
- **Passed**



HB 2255/SB 1029

- Also provides that nothing shall prevent a person who prescribes or dispenses a controlled substance from redisclosing information obtained from the Prescription Monitoring Program to another prescriber or dispenser who prescribes or dispenses a controlled substance to a recipient.
- **PASSED**



HB 2256/SB 1150

- Amends 54.1-3420.1 of the Code (proof of identity)
- Specifies that certain duties may be undertaken by the agent of the pharmacist.
- if person seeking to take delivery of a Schedule II drug is not the patient for whom the drug is prescribed and the person is not known to the pharmacist or his agent, the pharmacist or his agent shall either make a photocopy or electronic copy of the person's identification or record the full name and address of the person.



HB 2256/SB 1150

- Reduces the time for which the pharmacist must maintain records of the names and addresses or copies of the proof of identification of persons taking delivery of Schedule II drugs when they are not the person for whom the drug is prescribed from one year to one month.
- **PASSED**



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HB 2487

- Requires Board of Medicine to license and regulate naturopaths.
- Defines a naturopath as an individual, other than a doctor of medicine, osteopathy, chiropractic, or podiatry, who may diagnose, treat, and help prevent diseases using a system of practice that is based on the natural healing capacity of individuals, using physiological, psychological, or physical methods, and who may also use natural medicines, prescriptions, legend drugs, foods, herbs, or other natural remedies, including light and air.
- **Did Not Pass**



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SB 742

- Clarifies that pharmacists donating pharmaceutical services to patients of a free clinic shall be eligible for neighborhood assistance tax credits under specific circumstances.
- **PASSED**



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SB 878

- Would have placed pseudoephedrine into Schedule III.
- **Did Not Pass**



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HB 2083/SB 1317

- Bill allows a practitioner to prescribe antibiotic therapy to the sexual partner of a patient diagnosed with a sexually transmitted disease without the physical examination normally required.
- **Did Not Pass**



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SB 1420

- Requires, rather than authorizes, prescribers of controlled substances to notify law enforcement when they have reason to suspect that a person has obtained or attempted to obtain a controlled substance or prescription for a controlled substance by fraud or deceit.
- **Did Not Pass**



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- Board of Pharmacy website:
www.dhp.virginia.gov/pharmacy
- Email : pharmbd@dhp.virginia.gov



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Questions??